codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

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PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES

Prepared by the United States of America with the assistance of Australia, Canada, France, Germany, Italy, New Zealand, Norway, Spain, Sweden, Thailand, the International Dairy Federation, the International Federation of Environmental Health, and the International Commission on Microbiological Specifications for Foods

Governments and interested international organizations are invited to submit comments on the attached Draft Code at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Fifteenth Edition*) **to**: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 October 2006.**

I. INTRODUCTION

The control of hazards potentially associated with foods typically involves the application of control measures in the food continuum, from primary production, through processing, to consumption. In the current environment of system-based food safety controls that provide flexibility with the selection of control measures, validation of these control measures acquires increased importance. It is through the validation process that one demonstrates that the selected control measures actually are capable, on a consistent basis, of achieving the intended level of hazard control.

These guidelines present information on the concept and nature of validation, steps prior to validation, the validation process, priorities for validation, limitations to validation, and the need for re-validation. These guidelines also address the difference between validation and verification. Annex I provides explanatory material on the nature of control measures for food safety.

It is important to make a clear distinction between the role of industry[1] and the role of the competent authority in validating control measures. Industry is responsible for validation of control measures, while the competent authority ensures that industry has effective systems for validation and that control measures are appropriately validated. Governments may provide advice to industry on how to conduct validation studies and how validated control measures should be implemented. Governments or international organizations may also conduct validation studies in support of risk management decisions or provide information on control measures considered to be validated, especially where the resources are not available to conduct such studies (e.g., small and less-developed businesses).

II. SCOPE

These guidelines apply to validation of the full range of control measures intended to control biological, chemical or physical hazards within the entire food chain, which includes primary production, processing, distribution, storage, retail and foodservice, and consumer handling, and which apply for any type of food[2]. These guidelines are intended as advice to industry and governments on the validation of individual control measures, a limited combination of control measures or of entire sets of control measure combinations forming a food safety control system (e.g. HACCP, GHP).

The tools, techniques, and statistical principles that would be used to validate specific food control measures are beyond the scope of the current document. Advice on specific applications should be acquired from scientific organizations, competent authorities, process control experts or related sources of scientific expertise that can provide the specific principles and best practices upon which the validation of a control measure should be based.

III. DEFINITIONS[3]

Appropriate Level of Protection (ALOP): The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.[4]

Control Measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.[5]

Food Safety Control System: The combination of control measures implemented by industry that, when taken as whole, ensures that food is safe for its intended use.

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of health protection.[6]

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[1] For the purposes of this document, it is understood that industry includes all relevant sectors associated with the production, storage and handling of food, from primary production through retail and food service level (adapted from *Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius* and taken from *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management*, ALINORM 05/28/13).

[2] The focus of this document is the validation of elements of a food safety control system; however, the recommendations in this document also may be applied in the validation of other food hygiene measures.

[3] In many cases, existing definitions such as those contained in the SPS Agreement, the General Principles of Food Hygiene, HACCP Annex and the CCFH Risk Management document, were suitable for use in this document. In other cases, where a definition was too limiting outside of its original context (e.g., some HACCP Annex definitions), another definition was developed that was more suitable for use within the context of these guidelines.

[4] WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The term Member refers to countries.

[5] *International Recommended Code of Practice: General Principles of Food Hygiene,* CAC/RCP1-1969, Rev. 4 (2003), HACCP Annex.

[6] *Procedural Manual*, 15th Edition, Codex Alimentarius Commission.

Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.[7]

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before time of consumption that provides or contributes to an FSO or ALOP, as applicable.[8]

Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.[9]

Validation: Obtaining evidence that control measures, if properly implemented, are capable of controlling the hazard.[10]

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.[11]

IV. CONCEPT AND NATURE OF VALIDATION

Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control. Validation involves measuring performance against a desired outcome or target. As described in *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management*[12], the outcomes or targets may be expressed as, but are not limited to, FSO, PO, and PC. Microbiological criteria, or product or process criteria set in support of or independent of an FSO, PO, or PC may also be targets against which performance can be validated.

Validation is performed at the time new control measures or a new food safety control system is designed, or when changes indicate the need for re-validation (see section IX). Validation of control measures or food safety control systems is, when feasible, performed before their full implementation.

Relationship of Validation to Monitoring and Verification

Validation of control measures is different from monitoring and verification, which both take place after the validated control measures have been implemented. Monitoring and verification are the tools used to check whether the control measures are being adhered to and to demonstrate that they are operating as intended.

Monitoring is the on-going collection of information on a control measure at the step the control measure is applied (e.g., determining product temperature during cooking, cooling, or storage). The information establishes that the measure is meeting or functioning within established limits. Monitoring activities are typically focused on "real-time" measurements and are generally focused on the performance of a specific control measure.

Verification is used to determine that the control measures have been appropriately implemented and thus should achieve the level of hazard control required. Verification also provides an ongoing demonstration that the control measure continues to be effective. Verification occurs during or after operation through a variety of activities, including observation of monitoring activities and review of records to confirm that implementation of control measures is according to design. For example,

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[7] Ibid.
[8] Ibid.
[9] Derived from *International Recommended Code of Practice: General Principles of Food Hygiene,* CAC/RCP1-1969, Rev. 4 (2003), HACCP Annex, but was modified to apply to all control measures, whether or not a HACCP system is employed.
[10] Ibid.
[11] Ibid.
[12] ALINORM 05/28/13

observations that temperatures are taken at the frequency and in the manner specified would be a verification activity. Verification can focus on a single control measure (e.g., review of monitoring records to confirm control was achieved), or may evaluate combinations of control measures (e.g., environmental sampling to assess that sanitation measures were effective) or the entire food safety control system (e.g., microbiological analysis of end products for process control).

If validation demonstrates high confidence in hazard control (i.e., a control measure produces reduction of a pathogen well in excess of the reduction needed for hazard control), there may be less need to verify the safety of the product, for example, through end product testing.

V. STEPS PRIOR TO VALIDATION OF CONTROL MEASURES

Prior to the validation of control measures by the food establishment, a decision should be made regarding when, where and how validation can be accomplished.

Steps prior to validation include:

1) Identify the hazards that are intended to be controlled, taking into account all relevant information, including information from a risk assessment if available.

2) Identify the food safety outcome required.

   Factors to be considered include the existence of relevant FSOs, POs, PCs, and/or other outcomes or targets. For validation of an individual control measure or a defined combination of control measures, the desired outcome may be expressed in terms of a PC (e.g., reduction of the level of *Salmonella* by 99.999% (5-log reduction)). For validation of a food safety control system, the desired outcome can be expressed in terms of a PO established for the end product (e.g. maximum level of *Salmonella* to be <0.04 cfu/g or maximum frequency of 2 of 9 samples of fishery products containing between 100 and 200 mg/kg histamine) or an FSO established for the product at point of consumption (e.g., ≤ 100 *Listeria monocytogenes*/g at the time of consumption).

   In the absence of relevant food safety outcomes or targets established by a competent authority at a national or international level, targets should be identified by the individual food business operator (e.g., food manufacturer), as appropriate.

3) Identify the necessary control measures and determine which are to be validated. Factors that should be considered include:

   - Whether the validation is conducted to demonstrate capability of achieving a PC, PO, or FSO,
   - The importance of the control measure as it relates to achieving the expected control of the hazard (see example of heat treatment in canning below),
   - Whether a control measure can be validated by itself or whether combinations of certain control measures should be validated together.

   Examples of control measures that may need to be validated:

   - The control measures used at critical control points in a HACCP plan are generally among the ones that require validation.
   - Heat treatment step in a canning process. (Other control points coming before and after the canning process (e.g., steps to minimize microbial counts before canning and to prevent contamination after processing) are of lesser importance and may not require validation, though they contribute to the overall food safety control system. However, the degree of variation attributed to these other control points should be sufficiently known so that the validation of the heat treatment step will be adequate with the normal variation in the other control points.).

- On-farm practices (In some cases, on-farm practices will include control measures that are important to the safety of the finished product and these will need to be validated (e.g., implementation of pest control programs in egg laying houses to prevent the spread of pathogens among laying hens)).
- Hurdles within a hurdle technology approach (Where hurdle technologies are employed as the means of control, there will be multiple control measures that will need to be validated simultaneously).

4) Identify whether the control measure has previously been appropriately validated (e.g., a control measure required by a competent authority or validated by a competent authority or other national or international organization) or whether its performance is so well established for the application under consideration that validation should be considered complete. In either case, a food business operator must ensure that the conditions (e.g., raw materials, combinations of control measures, intended use, or distribution and consumption patterns) in the particular operation do not differ from the conditions under which the control measure was previously validated.

5) If necessary, prioritize control measures to be validated. In principle, most control measures used to control the various hazards potentially associated with a food product or product group should be validated. In practice, however, resource constraints may prohibit a comprehensive approach to validation and there may be a need to prioritize which control measures are actually validated. The following are some suggested parameters for determining how validation of control measures should be prioritized.

- <u>Level of risk</u>: The higher the likelihood that the inappropriate selection of a control measure will lead to a severe adverse health effect from a hazard, the more attention should be paid to assuring that the control measures selected are effective.

- <u>Importance of a control measure:</u> Validation priority should be given to the control measures in a food safety control system that have the greatest impact on overall control of a food safety hazard.

- <u>Historical experience</u>: If little or no experience exists with respect to the performance of a control measure in controlling a particular hazard, it becomes more important that validation be undertaken. For many food production and processing scenarios, there is extensive history that specific measures used to control food borne hazards are effective. Care is needed, however, to avoid assuming that a food production or processing system is safe based solely on historical experience. All relevant current information should be considered when evaluating the adequacy of historical information, as it may be outdated. For example, sampling and testing procedures used to obtain the original data may be insufficient in the context of current operating procedures. New strains of microbial pathogens may now exist that do not behave in the same manner as the strains of pathogens or surrogate microorganisms used for determining early food control processes. New epidemiological and/or clinical information may indicate that the control measures used in the past were less effective than previously thought.

VI. THE VALIDATION PROCESS

The precise approach to validation will depend, among other things, on the nature of the hazard, the nature of the product, the type of control measures or food safety control system selected to control the hazard, and the intended stringency of control of the hazard. While the specific validation approach employed may vary substantially, the goal remains the same across all products; i.e., demonstration and documentation that the control measures or food safety control systems employed are properly designed to provide the level of hazard control necessary.

<u>Approaches for validating control measures</u>:

The following approaches to validation may be used individually or in combination, as appropriate.

1. Reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure. Scientific or technical information needed to validate control measures may, in many instances, be available from many sources, including scientific literature, government regulations (and the scientific basis for mandated control measures), guidelines on GHP and HACCP control measures with a known history of good performance validated by competent authorities or independent scientific authorities, international standards or guidelines (e.g., Codex Alimentarius), and validation studies from industry and/or equipment manufacturers. However, if relying on such knowledge, care should be taken to ensure that the conditions of application in a food safety control system are consistent with those identified in the scientific information examined. For certain well-established processes (e.g., milk pasteurization at 72° C for 15 seconds), it may be sufficient to acquire only the data on the conditions or attributes specific for the operation in question that control the microbiological hazards of concern (e.g., establishing the necessary product temperature and holding time (dimensions and flow) to achieve a treatment of 72° C for 15 seconds).

2. Scientifically valid experimental trials that document the adequacy of the control measure. Laboratory challenge testing designed to mimic process conditions and pilot trials of particular aspects of a food processing system are validation techniques that are used commonly, particularly in food processing unit operations. Quantitative demonstration and documentation of appropriate log reduction of a specified pathogen by a specific microbiocidal process is an example of validation of a control measure by experimental trials. If the risk from a hazard is associated with growth of the pathogen to unacceptable numbers, then the conditions (e.g., product formulation, processing parameters, packaging or conditions of storage and distribution) that prevent the growth of the pathogen should be validated and documented using appropriately designed experimental trials. For example, if water activity must be controlled in a product to prevent growth of *S. aureus*, then validation can be achieved by documenting the water activity of that product under expected conditions of storage and distribution.

Scale up of laboratory-based experimental trials in a pilot plant are helpful in ensuring that the trials properly reflect actual processing parameters and conditions. However, this almost always requires the availability of appropriate non-pathogenic surrogate microorganisms, as viable pathogenic microorganisms should not be purposefully introduced into a food production facility. When surrogate microorganisms are used, validation should cover the appropriateness of the surrogates. Validation may have to be limited to a laboratory/pilot plant if there are no appropriate surrogate microorganisms available that can be used to acquire data under actual production conditions.

3. Collection of data during normal operating conditions in the food operation. Where this approach is used, biological, chemical or physical data relating to the hazards of concern are collected for a specified period (e.g., 3-6 weeks of full scale production)[13] during normal operating conditions in the food operation. For example, when the food safety control system is contingent upon the use of good veterinary practices in the field or good hygienic practices in the processing establishment, it may be necessary to validate these measures through the use of intermediate and/or finished product sampling and testing. Sampling should be based on the use of appropriate statistical sampling plans and validated testing methodology. Sufficient data should be collected so that appropriate statistical analysis can be carried out to assess the effectiveness of the control measure being validated; this can be impractical if the expected level of a hazard is low or the hazard occurs infrequently. Collection of data during normal operating conditions is often employed for complex processes, particularly when the level of control is not absolute. For example, this approach might be employed if a new antimicrobial rinse was being incorporated in a poultry chilling operation or a fresh-cut produce processing operation.

[13] The food business operator should dispose of or distribute product, as appropriate, produced during the validation period.

4. Statistically designed surveys. Statistically designed surveys can be used to validate control measures, the impact of which cannot be easily measured. For example, consumers' interpretation and response to safe handling labels that are used by a manufacturer or competent authority as a control measure to encourage the appropriate storage, preparation, or reuse of food products[14]. Surveys, focus groups or other means may be used to determine if the use of these labels is providing the intended degree of risk management. Accurate information on consumers' responses to labels and related information is an important tool when designing food safety systems which include consumer action (food handling) as a control measure. Care should be taken to ensure that the surveys or other activity provide data that is accurate and appropriate for use by an individual food business operator (e.g., food manufacturer) or competent authority.

5. Mathematical modelling. Mathematical modelling can be used to estimate the predicted performance of a control measure or combination of control measures, including taking into account variation of individual control measures. An example of this can be found in existing approaches used to validate the adequacy of a product's formulation (e.g., pH, water activity) and packaging to limit pathogen growth under variable storage, distribution and consumer handling conditions. This approach is most often employed to evaluate the effect of compositional variations, process modifications, or conditions of storage. Such models are typically developed from extensive, scientifically valid experimental trials (approach #2 above). Additional laboratory testing should be performed where necessary to ensure that the control measures suggested by the model are appropriate within the specific food safety control system.

Steps Involved in the Validation Process

The process of validating control measures includes the following steps:

- Complete the steps needed prior to validation.
- Assemble relevant validation information, including documentation of previous validation efforts, evaluate its appropriateness and feasibility for the control measure(s) under consideration and assess the need for supplementary validation.
- If needed, conduct validation studies.
- Document the findings of the validation studies.

Results of validation studies will either

- Indicate that the control measure is capable of adequately controlling the hazard and, thus, the measure can be implemented, or
- Indicate that the control measure is not capable of adequately controlling the hazard and should not be implemented. This may lead to re-evaluation of product formulation, process parameters, control measures, the food safety control system design, or other appropriate decisions/actions.

VII. LIMITATIONS TO VALIDATION

Validation depends on the application of the best science possible within practical economic and resource constraints. There are several factors, however, which place limits on the level of confidence of the validation. To some extent, limitations in validation can be compensated for through, for example, applying appropriate safety margins that adjust for the reduced level of confidence consequent with limited validation. The factors that may limit validation, some of which are related to the design of food safety control systems, include the following:

- Sampling Plans and Analytical Test Methods: When relevant to the chosen validation approach, the use of appropriate analytical methodology and statistically-based sampling plans is essential when

[14] The food business operator should encourage disposal or use of product, as appropriate, produced during the validation period.

validating control measures. The reliability of the validation study is directly related to the precision of the analytical methodology used and the statistical sampling plans or experimental designs employed to demonstrate that an outcome has been achieved. Sampling plans should be chosen to obtain the level of confidence desired in the validation study being undertaken, and taking into account any variability arising from the analytical methodology. To the greatest degree practical, experimental trials and studies should attempt to establish the variability associated with the control measure being validated, the food being considered, and the hazards being controlled.

- Resource Constraints: Validation activities are often resource intensive. Areas such as experimental trials, process capability studies, surveys, mathematical modelling or product sampling and analytical testing, particularly when applied in an appropriate statistical fashion, require significant resources. The extent to which sufficient resources are available and such activities can be undertaken will place limits on the ability to develop and validate food safety control measures. Necessary assistance (e.g., development of guidelines for industry, training and technical assistance), particularly to small and less-developed businesses, should be provided by national and international organizations.

- Steps Beyond the Control of the Validating Establishment: When validating an entire food safety control system, steps beyond the control of the establishment undertaking the validation (e.g., consumer handling and consumption practices) may introduce considerable uncertainty into the validation.

There will be a greater need for verification activities if the level of confidence regarding the results of the validation of the control measure is low. In those instances where the level of confidence is low and extensive verification is not feasible, the stringency of the control measure (or food safety control system) may have to be increased to provide an appropriate measure of assurance that the level of control is consistently met.

VIII. NEED FOR RE-VALIDATION

There are many changes that could lead to a need to re-validate a control measure, combination of control measures or the entire food safety control system. Examples include:

- The introduction in the food control system of a new control measure, technology or a piece of equipment that impacts the control of the hazard may necessitate that the system or parts of it be re-validated. Similarly, changes made in product formulation or the application of current control measures (e.g., time/temperature changes) may result in the need for re-validation of control measures. While minor changes are less likely to require re-validation of the control measures, multiple minor changes will usually result in the requirement for re-validation.

- Re-validation may be needed if the hazard associated with a food or ingredient changes as a result of (i) higher concentrations of pathogens than originally encountered and accounted for in the design, (ii) a change in response of a hazard to control (e.g., adaptation), (iii) emergence of a previously unidentified hazard, or (iv) new information indicating that the hazard is not being controlled to the level specified (e.g., new epidemiological findings or new analytical technologies).

- If monitoring or verification identifies failures above a pre-established rate for which a process deviation cause cannot be identified, re-validation may be needed. Non-compliance with monitoring or verification criteria may indicate a change in the parameters (i.e., the selection and specification of the control measures) on which the design of the food safety control system is based.

ANNEX I NATURE OF FOOD SAFETY CONTROL MEASURES

In the context of these guidelines, a broad range of control measures is used in the food continuum from primary production, processing and manufacturing, transport and distribution, storage and retail to preparation and consumption of the food. Control measures may include a variety of practices applied at various stages (e.g., good agricultural and animal production practices, good hygiene practices during manufacture and processing, good consumer handling practices). Control measures can also encompass sorting based on observation (e.g., culling damaged raw materials) and inspectional procedures (including product sampling and testing), as well as certain types of product labelling (e.g., consumer safe-handling statements). Because of this broad range of control measures, and recognizing that there may be different ways of categorizing control measures, one approach is to categorize control measures as illustrated below, with included examples.

Ensuring control of initial levels of hazards

- Employing good agricultural and animal production practices to minimize contamination during primary production.
- Using vaccines or competitive inhibition/exclusion to minimize microbial pathogens in animals for human consumption.
- Establishing requirement specifications with suppliers and requiring verifiable documentation (e.g., letters of guarantee or certificates of analysis) attesting to the status of microbiological, chemical and physical hazards in the incoming raw material.
- Using sampling and analyses, as necessary, and using appropriate methods based on established criteria to reject unacceptable ingredients or products.

Preventing an unacceptable increase of hazards

- Limiting growth of pathogens during processing, storage and transportation through proper temperature control (e.g., chilling and holding time and temperatures) and product formulation (e.g., acidification, reduction of water activity levels, use of preservatives, use of competitive microflora).
- Using shelf-life and other labelling instructions as a means of ensuring that the use or consumption of a product precedes an unacceptable increase of a hazard.
- Employing good cleaning and disinfection practices to minimize microbial or chemical loads in establishments and/or on processing equipment that would otherwise contaminate the product.
- Establishing good hygienic practices that minimize product contamination during or after manufacture and prevent cross-contamination between raw and cooked product.
- Using packaging techniques and materials to protect food from contamination.
- Implementing effective controls within the food processing environment (e.g., pest control, housekeeping, etc.)

Reducing or eliminating hazards

- Destroying pathogens (e.g., disinfectants, pasteurization, commercial sterilization, irradiation, freezing to kill certain parasites) or inactivating chemical hazards in the food.
- Removing pathogens, toxic chemicals or physical hazards in the food (e.g., physical inspection, sorting, trimming, washing, filtration, and centrifugation).